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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,598	03/08/2002	Jose Cibelli	P 0280688	1067

909 7590 01/26/2004  
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EXAMINER

BERTOGLIO, VALARIE E

ART UNIT PAPER NUMBER

1632

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/092,598

**Applicant(s)**

CIBELLI, JOSE

**Examiner**

Valarie Bertoglio

**Art Unit**

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                            | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)        | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: ____                                     |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 7 and 25-27, drawn to a method of making a mammalian nuclear transfer embryo comprising isolating a mammalian cell to be used as a nuclear transfer donor and genetically engineering said cell by knocking out a gene required for differentiation into a particular lineage, classified in class 800, subclass 24.
- II. Claim 8, drawn to a method of making a mammalian nuclear transfer embryo comprising isolating a mammalian cell to be used as a nuclear transfer donor and genetically engineering said cell by recombinantly inserting a suicide gene operably linked to a specific promoter, classified in class 800, subclass 24.
- III. Claims 9-20,28-50,53,54,56-62 and 70-72, drawn to a method of making a mammalian nuclear transfer embryo comprising isolating a mammalian cell to be used as a nuclear transfer donor and genetically engineering said cell by stably transfecting said cell with at least one oligonucleotide that encodes an RNA molecule that interferes with the expression of a gene, classified in class 800;536, subclass 24,24.5.
- IV. Claims 63-65, drawn to a method of therapy using cells that are derived from a genetically modified nuclear transfer embryo, classified in class 424, subclass 93.21.

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- V. Claims 66-68, drawn to a method of transplantation using tissues derived from genetically modified nuclear transfer embryo, classified in class 435, subclass 1.1.

Claims 1-6,21-24,51,52,55 and 69 link(s) inventions I-III. The restriction requirement to the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-6,21-24,51,52,55 and 69. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

The methods of each of inventions I-III are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. The methods of Invention I require knocking out a gene, using gene-targeting technology. The methods of Invention II require random transgene insertion technology. The methods of Invention III require RNAi or antisense RNA technology. No one method is required for the other. Each method results in a materially distinct embryo.

Inventions I-III and Invention IV are patentably distinct because the methods of Inventions I-III can be used to generate a nuclear transfer embryo while the methods of Invention IV can be used to treat disease. The methods of Inventions I-III are not necessary for those of Invention IV. Inventions I-III are each classified differently from Invention IV. The burden required to search any of Inventions I-III and Invention IV together would be undue.

The methods of each of Inventions I-III and of Invention V are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. Inventions I-III and Invention V are patentably distinct because the methods of Inventions I-III can be used to generate a nuclear transfer embryo while the methods of Invention V can be used to transplant tissue. The methods of Inventions I-III are not necessary for those of Invention V. Inventions I-III are each classified differently from Invention V. The burden required to search any of Inventions I-III and Invention V together would be undue.

The methods of each of Inventions IV and V are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. The methods of Invention IV involve treatment of a disease state using cells. The methods of Invention V involve transplant of a tissue. The methods of Invention IV are not necessary for those of Invention V. Invention IV is classified differently from Invention V. The burden required to search Inventions IV and V together would be undue.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on Mon-Fri 6:00-2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Note: After January 13, 2004, the Examiner may be reached at (571) 272-0725, and should the Examiner be unavailable, inquiries may be directed to Deborah Reynolds, SPE of Art Unit 1632 at (571) 272-0734.

*Deborah Crouch*  
DEBORAH CROUCH  
PRIMARY EXAMINER  
GROUP 1800  
1630

Valarie Bertoglio  
Examiner  
Art Unit 1632